OFFICE OF REGULATORY POLICY

DIDP Procedures for Processing NDA and NDA Supplement Approval Letters and Action Packages to Be Posted on the Internet

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PURPOSE

- This MAPP outlines the procedures in the Division of Information Disclosure Policy (DIDP) for processing and redacting approval letters and action packages for new drug applications (NDAs) and NDA efficacy supplements. After redaction in DIDP, the approval letters and action packages are posted on the Center for Drug Evaluation and Research (CDER) Internet web site.

BACKGROUND

- Information about approved drug products is of considerable interest to the public. Therefore, it is important that CDER make this information publicly available as quickly as possible after a drug product is approved.

REFERENCES

- *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book), 21st Edition
- CDER MAPP 4520.1, Communicating Drug Approval Information
- Freedom of Information Act, 5 U.S.C. section 552

DEFINITIONS

- **Action Package:** A compilation of (1) FDA-generated documents related to the review of an NDA, ANDA, or efficacy supplement, from submission to final action;

(2) documents, including meeting minutes and pharmacology reviews, pertaining to the format and content of the application generated during drug development; and (3) labeling submitted by the applicant. (See CDER MAPP 4520.1.)

- **CDER Internet Web Page:** A publicly accessible Internet web page containing information posted by CDER. The URL for the CDER Internet web page is http://www.fda.gov/cder. Only information disclosable to the public is available on the CDER Internet Web Page.

- **DFS:** The Division File System, the official electronic signing and archiving system used in the CDER Office of New Drugs. (See CDER MAPP 4520.1.)

- **First Reviewer:** A Consumer Safety Officer (CSO) or Regulatory Counsel in DIDP who performs the first review and redaction of an NDA approval letter or action package.

- **New Drug Application (NDA):** An application for the review and approval of a new drug.

- **New Molecular Entity (NME):** An active moiety that has not previously been approved (either as the parent compound or as a salt, ester, or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination. (See the Orange Book.)

- **Second Reviewer:** A CSO or Regulatory Counsel in DIDP who performs the second review and redaction of an NDA approval letter or action package.

POLICY

- DIDP authorizes posting NDA approval letters and action packages on the CDER web site to provide the public with timely information on approved drug products.

- Action packages will be reviewed and redacted in DIDP based on the following priority:

  (1) Newest NMEs
  (2) Newest NDAs
  (3) NDAs approved in 2002, in reverse chronological order (most recent approval first)
  (4) NDAs approved between 1998 and 1999, in reverse chronological order, when Freedom of Information (FOI) requests asking for the approval information are pending in DIDP
  (5) Newest efficacy supplements
  (6) Efficacy supplements approved between 2000 and 2002, in reverse chronological order, by date of approval
  (7) Efficacy supplements approved between 1998 and 1999, in reverse chronological order, when FOI requests asking for the approval information are pending in DIDP

- In unusual circumstances, the Director of DIDP may assign priority to the review and redaction of an action package outside of the priority list, for example, when the approval will have a significant impact on the public health or when the approval has generated or is likely to generate an extraordinary amount of public interest.

- DIDP expects to receive from the appropriate review division two copies of each NDA action package within 10 business days of approval. If DIDP does not receive an action package within 10 days of approval, the PDUFA Team Leader will work with the review division to ensure prompt receipt.

- DIDP anticipates that it will take approximately 5 business days for the CDER Medical Library to post each electronic action package on the CDER Internet web page after it receives notification from DIDP that the redacted package is ready for posting. If the Medical Library does not post an action package within 5 business days of being notified that the package is ready for posting, the Project Specialist will work with the Medical Library to ensure prompt posting.

- DIDP's goal is to have newly approved NME action packages posted on the CDER Internet site within 10 weeks of approval and newly approved NDA action packages posted within 20 weeks of approval.

- DIDP uses a two-person redaction process to (1) ensure that materials posted on the CDER web site do not contain information exempt from disclosure and (2) encourage thoughtful discussion and consideration of redaction issues.

- Throughout the redaction process, the CSOs, Regulatory Counsels, Team Leaders, and the DIDP Director communicate about the releasability of information and work together to resolve any issues.

- CSOs and Regulatory Counsels who have demonstrated sufficient independence in redacting packages will perform the first redaction of approval letters and action packages. The PDUFA Team Leader or a CSO or Regulatory Counsel who has demonstrated independence will perform the second redaction of all such records.

- DIDP receives many FOI requests for NDA action packages. When an NDA action package is posted on the CDER Internet web page, the CSO or Regulatory Counsel in DIDP responsible for related FOI requests will notify all requesters that the action package is available on the CDER Internet web page. In such cases, DIDP will not charge the requester for responding to the FOI requests unless the requester specifically asks for additional information or a paper copy of the action package.

- DIDP will promptly investigate any allegation that DIDP authorized the posting of information exempt from disclosure on the CDER Internet web site. Immediately upon notification of an allegation, DIDP will request that all records containing the allegedly exempt information be removed from the Internet. Such removal does not constitute an admission that exempt information was posted on the Internet. Rather, removal of the allegedly exempt information from the Internet allows DIDP to thoughtfully consider the allegation and review the record at issue to determine

whether any exempt information was released. DIDP will work with the Office of Chief Counsel (OCC) to resolve any disputes stemming from such allegations. Once the dispute is resolved, DIDP will request that appropriate information be reposted on the Internet web site.

RESPONSIBILITIES AND PROCEDURES

APPROVAL LETTERS

The Project Specialist will:

- Receive the letter by DFS e-mail
- Prepare the letter for redaction
- Enter tracking information in the NDA Approvals Tracking System
- Save the letter to the shared area at efoi1/DIDP Letter Review using the following naming convention: NDA#ini.pdf
- Notify the First Reviewer that the letter is available and ready for redaction

The First Reviewer will:

- Retrieve the letter from the shared area
- Redact the letter
- Consult with other CSOs, Regulatory Counsels, Team Leaders, and DIDP Director, as appropriate, to resolve any questions about the releasability of information
- When complete, save the letter to the shared area at efoi1/DIDP Letter Review/REV1 using the following naming convention: NDA#rev1.pdf
- Inform the PDUFA Team leader and Project Specialist and provide the file name by e-mail when redactions are complete

The Project Specialist will:

- Update NDA Approvals Tracking System

The Second Reviewer will:

- Retrieve the letter from the shared area
- Perform second redaction of the letter
- Consult with other CSOs, Regulatory Counsels, Team Leaders, and DIDP Director, as appropriate, to resolve any questions about releasability of information
- When complete, save the letter to the shared area at efoi1/DIDP Letter Review/REV2 using the following naming convention: NDA#rev2.pdf
- Inform the Project Specialist and provide the file name by e-mail when redactions are completed

The Project Specialist will:

- Retrieve the letter and save it to the shared area at FOIREAD/APPROVALS/LETTERS using the following naming convention: NDA#ltr.pdf

- Notify the Medical Library by e-mail that the letter is ready to be posted and provide the file name
- Ensure that the letter is posted to the CDER web site in a timely fashion
- Update NDA Approvals Tracking System

The Director, DIDP, and Team Leaders will:

- Help resolve any questions about the releasability of information
- Perform random quality checks of redacted approval letters

ACTION PACKAGES

The PDUFA Team Leader will:

- Ensure the receipt of two copies of an NDA action package in DIDP within 10 business days of approval. If an action package is not received in DIDP within 10 business days of approval, the PDUFA Team Leader will contact the division project manager (PM) and will arrange for prompt receipt of the package. If the package is not received by DIDP within 15 business days of approval, the PDUFA Team Leader will notify the Directors of DIDP and the review division and will facilitate the immediate receipt of the action package.

The Paralegal Specialist will:

- Receive two copies of the NDA action package by interoffice mail
- Start the NDA Tracking Information Form for the action package, and place it on the action package
- Provide a copy of the NDA Tracking Information Form to the Project Specialist
- Place two copies of the package on the appropriate DIDP shelf
- Notify the PDUFA Team Leader by e-mail that the action package is available and ready for redaction

The Project Specialist will:

- Enter tracking information into the NDA Approvals Tracking System

The PDUFA Team Leader will:

- Assign the action package for review to the First Reviewer by e-mail; copy the Project Specialist on the e-mail. Action packages will be assigned for review based on the priorities described in the Policy section of this MAPP. Action packages waiting for second review will be assigned a higher priority than packages waiting for first review.

The Project Specialist will:

- Receive e-mail from PDUFA Team Leader and update NDA Approvals Tracking System

The First Reviewer will:

- Retrieve the action package from DIDP shelves
- Note the date on which redactions begin on the NDA Tracking Information Form
- Notify the Project Specialist by e-mail of the date on which the redaction began

The Project Specialist will:

- Update NDA Approvals Tracking System

The First Reviewer will:

- Redact action package
- Consult with other CSOs, Regulatory Counsels, Team Leaders, and the DIDP Director, as appropriate, to resolve any questions about the releasability of information
- Note on the NDA Tracking Information Form the date redactions are completed
- Notify the Project Specialist by e-mail of the date redactions are completed
- Place the action package back on DIDP shelves

The Project Specialist will:

- Update NDA Approvals Tracking System

The PDUFA Team Leader will:

- Assign the action package for review to the Second Reviewer by e-mail; copy the Project Specialist on the e-mail. Action packages will be assigned for review based on the priorities described in the Policy section of this MAPP. Action packages waiting for second review will be assigned a higher priority than packages waiting for first review.

The Project Specialist will:

- Receive e-mail from PDUFA Team Leader and update NDA Approvals Tracking System

The Second Reviewer will:

- Retrieve the action package from DIDP shelves
- Note the date on which redactions begin on NDA Tracking Information Form
- Notify Project Specialist by e-mail of the date redactions begin

The Project Specialist will:

- Update NDA Approvals Tracking System

The Second Reviewer will:

- Redact action package

- Consult with other CSOs, Regulatory Counsels, Team Leaders, and the DIDP Director, as appropriate, to resolve any questions about the releasability of information
- Note the date on which redactions are completed on NDA Tracking Information Form
- Return the action package to the First Reviewer
- Notify the Project Specialist and the PDUFA Team Leader by e-mail of the date that redactions are completed

The Project Specialist will:

- Update NDA Approvals Tracking System

The First Reviewer will:

- Receive the completed action package from the Second Reviewer, review any changes made in the redaction of the action package, prepare the action package for scanning, and place a copy of the taped action package in the scanning box
- Record the date the action package was put in the scanning box
- Notify the Secretary that the action package is ready to be scanned into electronic format
- Keep the original taped copy of the action package until the package is returned from the scanner

The Secretary will:

- Coordinate scanning of the action package
- Once the original package is returned from the scanner, give the CD with electronic version of action package, as well as the returned copy of the taped action package, to the Project Specialist
- Record the date on which the package is returned from the scanner

The Project Specialist will:

- Notify DIDP staff that the action package has returned from the scanner

The First Reviewer will:

- Once notified that the action package has returned from the scanner, give the original NDA Tracking Information Form and taped copy of the action package to the Project Specialist

The Project Specialist will:

- Save the action package to the shared area at FOIREAD/APPROVALS/APPROVAL PACKAGES/NDA
- Notify the Medical Library and DIDP CSOs by e-mail that the action package is ready to be posted on CDER web site and provide the file name for the package
- Update NDA Approvals Tracking System
- Ensure that the action package is posted to the CDER web site in a timely fashion
- Update the NDA Approvals Tracking System to show that the action package is posted

- Place taped copy of action package and the completed original NDA Tracking Information Form on the DIDP shelves
- Place the copy of the taped action package, which has been returned by the scanner, in the shred box

The Director, DIDP, and the Team Leaders will:

- Provide input at all stages on any questions or possible issues with the redaction process
- Perform random quality checks of redacted action packages

DISPUTES

The Director, DIDP will:

- Immediately after being notified of an allegation that DIDP authorized the posting of exempt information in an approval letter or action package, request that the record containing allegedly exempt information be removed from the CDER Internet web page

The PDUFA Team Leader will:

- Upon notification that a record in an NDA action package was removed from the CDER Internet web page because an allegation was made that DIDP authorized the posting of exempt information, review the record at issue to determine whether any exempt information was released

The Director, DIDP will:

- Work with OCC to resolve any disputes stemming from allegations that DIDP authorized the posting on the CDER Internet web page of exempt information in an NDA action package. Once the dispute is resolved, the Director will request that appropriate information be reposted on the Internet web site.

EFFECTIVE DATE

This MAPP is effective upon date of publication.